

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



IN RE APPLICATION OF: Elizabeth King, et al. :

APPLICATION NO.: 09/425,622

Examiner: J. Spear  
Group Art Unit: 1615

FILING DATE: October 22, 1999

TITLE: Controlled-Release Pharmaceutical  
Formulations

I hereby certify that this correspondence  
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this 15<sup>th</sup> day of January 2003

Sir:

By 

Response To Non-Final Office Action

This is in response to the non-Final Office Action dated July 16, 2002 in the  
above-identified application, the term for response having been extended three (3)  
months by including the appropriate fee and petition herewith.

In response to the Office Action, please make the following changes to the  
application:

In the claims:

01 17 42. (Once Amended) A formulation as claimed in claim 41, wherein  
the core further comprises a buffering agent.

SUB  
01 14 Cancel claims 44 and 45 without waiver or prejudice.

02 14 46. (Once Amended) A process for the production of a sustained-  
release formulation comprising a cGMP PDE-5 inhibitor embedded in a matrix from  
which it is released by diffusion or erosion, which comprises the steps of:

- (a) mixing the cGMP PDE-5 inhibitor with a matrix material, and pressing into  
tablets;
- (b) forming a core comprising the cGMP PDE-5 inhibitor and then coating the  
core with a release rate-controlling membrane; or
- (c) forming a core containing the cGMP PDE-5 inhibitor and then coating the  
core with a coating impermeable to the cGMP PDE-5 inhibitor;